ATTORNEY DOCKET No. 22118.0002U2

PATENT

PAGE 1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SEP 1 0 2008

In re Application of:	) •	24/3		
James Skinner	Art Unit:	3762		
Application No. 10/767,861	) Confirmation No.	2987		
Filing Date: January 29, 2004	)	George C. Manuel		
For a: "METHOD AND SYSTEM FOR DETECTING AND/OR PREDICTING CEREBRAL DISORDERS"	) Examiner: )			
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# AMENDMENT AND RESPONSE TO OFFICE ACTION TRANSMITTAL

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 NEEDLE & ROSENBERG, P.C. 999 Peachtree Street, Suite 1000 Atlanta, Georgia 30309 Customer Number 23859

Sir:

Transmittal herewith is/are the following in the above-identified application:

Amendment/Response	tion to Extend Time plemental Declaration minal Disclaimer
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			CLAIMS AS AMENI	PRESENT	RATE	ADDITIONAL
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	AFTER AMENDME		22.	3		\$200.00
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<u> </u>	\$120	\$450	121	O 68 619 6	3,27, \$1.28) -	- \$685.00
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ATTORNEY DOCKET No. 22118.0002U2 PATENT PAGE 2

Paymer	nt:
	A check in the amount of \$ is enclosed.
Ø	Payment by credit card in the amount of \$685.00 for the fees designated below.  (Form PTO-2038 enclosed).  WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit warning: Information and suphorization on PTO-2038.
	The Commissioner is authorized to charge our Deposit Account No. 14-0629 in the amount of \$ to cover the above-listed additional fees. A duplicate copy of this transmittal is enclosed.
Ø	In the event of an overpayment or improper payment of a required fee, the Commissioner is authorized to charge or credit our Deposit Account No. 14-0629 as required to correct the error.
	Respectfully submitted,
	NEEDLE & ROSENBERG, P.C.
	Charley E Brown, Registration No. 52,658
999 Sui Atl: (67	Peachtree Street te 1000 anta, Georgia 30309 8) 420-9300 (telephone) 8) 420-9301 (facsimile)
[]	CERTIFICATE OF MAILING UNDER 37 C.F.R. 6 1.8  Thereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed at MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.  An Alaxama M. Youlfan Dollan Date
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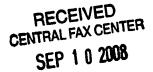
### CENTRAL FAX CENTER

SEP 1 0 2008

	Application No.	Applicant(s)				
	10/767.861	SKINNER, JAMES				
Notice of Allowability	Examiner	Art Unit				
	George Manuel	3762				
— The MAILING DATE of this communication appeal all claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PYOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this ap or other appropriate communication IGHTS. This application is subject t	plication. If not included n will be mailed in due course. THIS				
1. This communication is responsive to the Terminal Disclain	ner filed, 2/8/07.					
2. The allowed claim(s) is/are 1-25.						
3. Acknowledgment is made of a claim for foreign priority uses) All b) Some* c) None of the:  1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have 1. Certified copies of the certified copies of the priority documents have 1. Certified copies not received:  Applicant has THREE MONTHS FROM THE *MAILING DATE* noted below. Failure to timely comply will result in ABANDON'S THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4. A SUBSTITUTE OATH OR DECLARATION must be subminified in the complex of the priority of the certified copies not received:  5. CORRECTED DRAWINGS (as "replacement sheets") must be completed by the Notice of Draftsper 1) hereto or 2) to Paper No./Mail Date  [b) including changes required by the attached Examiner Paper No./Mail Date  Identifying Indicts such as the application number (see 37 CFR) each sheet. Replacement sheet(s) should be labeled as such in	e been received. e been received in Application No cuments have been received in this of this communication to file a reply MENT of this application	rational stage application from the complying with the requirements  R'S AMENDMENT or NOTICE OF ation is deficient.  -948) attached  Office action of sings in the front (not the back) of				
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.						
Attachment(s)  1. Notice of References Cited (PTO-892)	5. Notice of Informal	Patent Application				
2. Notice of Draftperson's Patent Drawing Review (PTO-948)	<u>=</u>	y (PTO-413),				
3. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 5/31/07	7. Examiner's Amend					
Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. 🛛 Examiner's Statem	nent of Reasons for Allowance				
Si Citroglical material	9. 🔲 Other					
U.S. Potent and Trademark Office		·				

Application/Control Number: 10/767,861

Art Unit: 3762



Page 2

#### **DETAILED ACTION**

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charley Brown on 5/30/07.

The application has been amended as follows:

In claim 1, line 6, before "determining" insert --to reduce noise in the data series--.

In claim 12, line 6, replace "within" with -outside-, line 9, replace "outside" with - within-.

In claim 23, line 7, before "determining" insert —to reduce noise in the data series—.

#### Allowable Subject Matter

Claims 1-25 are allowed.

The following is an examiner's statement of reasons for allowance:

In a method of detecting or predicting a cerebral disorder, using a data series based on a reduced noise data series determined slope or a noise interval within a predetermined range as claimed is not taught nor suggested by the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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Art Unit: 3762

Page 3

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ortel et al (US 2003/0104493) disclose: if it is determined that a value or a slope at or over a particular time in a time-dependent measurement profile is beyond a corresponding predetermined value or slope threshold, then the test sample is flagged as being a sample from an individual with an increased likelihood of having antiphospholipid syndrome in brain tissue.

However, there lacks a teaching or suggestion in Ortel et al to reduce noise in a data series by determining a slope of the data series.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

/George Manuel / George Manuel Primary Examiner Art Unit: 3762

	Application No.	Applicant(s)				
Examiner-Initiated Interview Summary	10/767,861	SKINNER, JAMES				
Examiner-invaced interview duminary	Examiner	Art Unit				
·	George Manuel	3762				
All Participants:	Status of Application:					
(1) <u>George Manuel</u> .	(3)	·				
(2) <u>Charley Brown</u> .	(4)					
Date of Interview: <u>30 May 2007</u>	Time:					
Type of Interview:  ☐ Telephonic ☐ Video Conference ☐ Personal (Copy given to: ☐ Applicant ☐ Applic  Exhibit Shown or Demonstrated: ☐ Yes ☐ No If Yes, provide a brief description:	ant's representative)					
Part I. Rejection(s) discussed:						
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Claims discussed:						
1, 12, 23	•					
Prior art documents discussed:						
Ortel et al (US 2003/0104493)						
Part II.		•				
SUBSTANCE OF INTERVIEW DESCRIBING THE GENE						
It was agreed to amend claims 1, 12 and 23 by Examiner's Ame prior art of record	endment to clearly define Applicar	nt's invention and to avoid the				
Part III.						
<ul> <li>It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability.</li> <li>It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.</li> </ul>						
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(Examiner/SPE Signature) (Application	nt/Applicant's Representative S	Signature – if appropriate)				

U.S. Patent and Tradement Office PTOL-413B (04-03)

Examiner initiated interview Summary

Paper No. 20070530

Issue Classification	Application/Control No.	Applicant(s)/Patent under Reexamination		
	10/767,861	SKINNER, JAMES		
	Examiner	Art Unit		
	George Manuel	3762		

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U.S. Patent and Trademark Office

Part of Paper No. 20070530

Page 1 of 1



#### United States Patent and Trademark Office

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**Bib Data Sheet** 

. CONFIRMATION NO. 2987

SERIAL NUMBER 10/767,861	FILING OR 371(c) DATE 01/29/2004 RULE	C	:L <b>ASS</b> 600	GROU	ROUP ART UNIT 3762			ATTORNEY DOCKET NO. 22118.0002U2		
APPLICANTS  James Skinner	APPLICANTS  James Skinner, Bangor, PA;									
** CONTINUING DATA **********************************										
	EIGN FILING LICENSE		ED SMALL E	NTITY	** '					
met Verified and	Foreign Priority claimed									
ADDRESS / 23859			•							
TITLE Method and system	for detecting and/or pred	li <b>cting c</b> e	rebral disorder	S						
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Search Notes	

Application/Control No.	Applicant(s)/Patent under Reexamination					
10/767,861	SKINNER, JAMES					
Examiner	Art Unit					
George Manuel	3762					

SEARCHED						
Class	Subclass	Date	Examiner			
600	300, 509, 544, 545	5/30/2007	GM			
435	7.9	5/30/2007	GM			
128	920	5/30/2007	GM			
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ואו	INTERFERENCE SEARCHED						
Class	Subclass	Date	Examiner				
600	300, 509	5/30/2007	GM				
600	544, 545	5/30/2007	GM				
128	920	5/30/2007	GM				
	Interference Search History Printout		GM				

SEARCH NOTES (INCLUDING SEARCH STRATEGY)			
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U.S. Patent and Trademark Office

Part of Paper No. 20070530

#### ATTORNEY DOCKET NO. 22118.0002U2 Application No. 10/767,861

In accordance with the provisions of M.P.E.P. § 2001.06(b) and 37 C.F.R. § 1.98(b)(3), Applicants would like to bring to the attention of the Examiner the existence of the co-pending patent application(s) identified below, which were filed in the United States Patent and Trademark Office:

	Application No.	Date Filed	<u>Inventors</u>	Attorney Docket No.
1.	11/243,834	October 5, 2005	Skinner et al.	22118.0002U3
2.	60/824,170	August 31, 2006	Skinner et al.	22118.0011U1

The pending application(s) are stored in the Image File Wrapper (IFW) system of the USPTO. Accordingly, copies of the cited specification(s), including the claims and drawings thereof, are not enclosed in accordance with the waiver to 37 CFR 1.98(a)(2)(iii) dated September 21, 2004.

This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(c), in that neither a final Office Action nor a Notice of Allowance has been mailed to Applicants. Accordingly, Applicants enclose the fee required under 37 C.F.R. § 1.97(c)(2).

Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

ATTORNEY DOCKET NO. 22118.0002U2 Application No. 10/767,861

A Credit Card Payment Form in the amount of \$180.00, representing the fee under 37 C.F.R. § 1.17(p), is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

/Charley F. Brown #52.658/ Charley F. Brown Registration No. 52,658

NEEDLE & ROSENBERG, P.C. Customer Number 23859 (678) 420-9300 (678) 420-9301 (fax)

Electronic Patent Application Fee Transmittal					
Application Number:	10	767861		<u>.                                    </u>	
Filing Date:	29	-Jan-2004			
Title of Invention:	Method and system for detecting and/or predicting cerebral disorders				erebrat disorders
First Named Inventor/Applicant Name:	James Skinner				
Filer:	Charley F. Brown				
Attorney Docket Number:	22118.0002U2				
Filed as Large Entity					
Utility Filing Fees					
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:					
Pages:		,	•		11.7
Claims:				VV	-
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					
Post-Allowance-and-Post-Issuance:					
Extension-of-Time:					

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
	Total in USD (\$)			180

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Electronic Acknowledgement Receipt				
EFS ID:	1827203			
Application Number:	10767861			
International Application Number:				
Confirmation Number:	2987			
Title of Invention:	Method and system for detecting and/or predicting cerebral disorders			
First Named Inventor/Applicant Name:	James Skinner			
Customer Number:	23859			
Filer:	Charley F. Brown			
Filer Authorized By:				
Attorney Docket Number:	22118.0002U2			
Receipt Date:	31-MAY-2007			
Filing Date:	29-JAN-2004			
Time Stamp:	16:14:51			
Application Type:	Utility			
Payment information:		··· ···· ···· ·		
Submitted with Payment	yes			
Payment was successfully received in RAM \$180				
RAM confirmation Number 1065				
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

#### **EAST Search History**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	7	((cerebral or brain) and disorder and data and slope and (detect\$4 or predict\$4)).clm.	US-PGPUB	OR	ON	2007/05/30 16:15

Application Number	10/767,861	ntrol No.	Re	pilcant(s)/Patent ( examination KINNER, JAMES	under
Document Code - DISQ		Internal D	oc	ument – DÇ	NOT MAIL
TERMINAL DISCLAIMER	⊠ APPROVI	ED		☐ DISAPPI	ROVED
Date Filed : 2/8/07	This patent is subject to a Terminal Disclaimer		t		
Approved/Disapproved b	y:	•			
ANDRE ROBINSON					

U.S. Patent and Trademark Office

### ARNALL GOLDEN & GREGORY RECEIVED CENTRAL FAX CENTER

SEP 1 0 2008

ATTORNEY DOCKET NO. 22118.0002U2 APPLICATION NO. 10/767,861 ELECTRONIC FILING

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)
James Skinner	) Art Unit: 3762
Application No.: 10/767,861	Examiner: George C. Manuel
Filing Date: January 29, 2004	) Confirmation No.: 2987
For: METHOD AND SYSTEM FOR DETECTING AND/OR PREDICTING CEREBRAL DISORDERS	) ) )

#### RESPONSE TO OFFICE ACTION

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C. 999 Peachtree Street, Suite 1000 Atlanta, Georgia 30309 Customer Number 23859

Sir:

This paper is in response to the Office Action dated August 8, 2006 that issued in the above-identified patent application. In light of the following remarks, it is respectfully requested that the application be reconsidered and placed in condition for allowance.

Listing of the Claims begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

#### LISTING OF CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Original) A method of detecting or predicting a cerebral disorder, comprising the steps of:

analyzing input biological or physical data using a data processing routine including a set of application parameters associated with biological data correlating with the cerebral disorder to produce a data series,

determining whether a slope of the data series is smaller than a predetermined value; if the slope is less than a predetermined value, setting the slope to a predetermined number; and

using the data series to detect or predict the onset of the cerebral disorder.

- 2. (Original) The method of claim 1, wherein the cerebral disorder is bovine spongioform encephalitis.
- 3. (Original) The method of claim 1, wherein the cerebral disorder is Alzheimer's disease.
- 4. (Original) The method of claim 1, wherein the data processing routine uses the following algorithm to produce a data series PD2i:

PD2i  $\subseteq \log C(n, r, nref^*)/\log r$ 

where ⊆ means scales as, C is the correlation integral for PD2i in which n equals the data length, r equals the scaling range, and nref\* equals a location of the reference vector for estimating the scaling region slope of log C/log r in a restricted small log-r range that is devoid of the effects of non-stationary data.

- 5. (Original) The method of claim 1, wherein the predetermined value is approximately 0.5.
- 6. (Original) The method of claim 1, wherein the predetermined number is zero.

 (Original) The method of claim 1, further comprising: determining a noise interval within the data series; and

if the noise interval is within a predetermined range, dividing the data series by another predetermined number and repeating the step of analyzing to produce new values for the data series.

- 8. (Original) The method of claim 7, wherein the other predetermined number is two.
- 9. (Original) The method of claim 7, wherein the predetermined range is -x to +x, where x is any number.
- 10. (Original) The method of claim 9, wherein the predetermined range is -5 to +5.
- 11. (Original) The method of claim 1, wherein the input biological or physical data includes electrophysiological data.
- 12. (Original) A method of detecting or predicting cerebral disorder, comprising the steps of: analyzing input biological or physical data using a data processing routine including a set of application parameters associated with biological data correlating with the cerebral disorder to produce a data series;

determining a noise interval within the data series; and

if the noise interval is within a predetermined range, dividing the data series by a predetermined number and repeating the step of analyzing to produce new values for the data series; or

if the noise interval is outside the predetermined range, using the data series to detect or predict the onset of cerebral disorder.

13. (Original) The method of claim 12, wherein the cerebral disorder is bovine spongioform encephalitis.

- 14. (Original) The method of claim 12, wherein the cerebral disorder is Alzheimer's disease.
- 15. (Original) The method of claim 12, wherein the data processing routine uses the following algorithm to produce a data series PD2i:

PD2i  $\subset \log C(n, r, nref*)/\log r$ 

where ⊆ means scales as, C is the correlation integral for PD2i in which n equals the data length, r equals the scaling range, and mref\* equals a location of the reference vector for estimating the scaling region slope of log C/log r in a restricted small log-r range that is devoid of the effects of non-stationary data.

- (Original) The method of claim 12, wherein the predetermined number is two.
- 17. (Original) The method of claim 12, wherein the predetermined range is -x to +x, where x is any number.
- 18. (Original) The method of claim 17, wherein the predetermined range is -5 to +5.
- 19. (Original) The method of claim 12, further comprising: determining whether a slope of the data series is smaller than a predetermined value; and if the slope is less than a predetermined value, setting the slope to another predetermined number.
- 20. (Original) The method of claim 19, wherein the predetermined value is approximately 0.5.
- 21. (Original) The method of claim 19, wherein the other predetermined number is zero.
- 22. (Original) The method of claim 12, wherein the biological or physical data includes electrophysiological data.

23. (Previously Presented) method of detecting or predicting a cerebral disorder selected from the group consisting of human prion diseases, cardiovascular dementia, traumatic dementia, and genetic dementia, the method comprising the steps of:

analyzing input biological or physical data using a data processing routine including a set of application parameters associated with biological data correlating with the cerebral disorder to produce a data series;

determining whether a slope of the data series is smaller than a predetermined value;

if the slope is less than a predetermined value, setting the slope to a predetermined number; and

using the data series to detect or predict the onset of the cerebral disorder.

24. (Previously Presented) The method of claim 23, wherein the data processing routine uses the following algorithm to produce a data series PD2i;

PD2i ⊆ log C(n, r, nref\*)/log r

where  $\subseteq$  means scales as, C is the correlation integral for PD2i in which n equals the data length, r equals the scaling range, and nref\* equals a location of the reference vector for estimating the scaling region slope of log C/log r in a restricted small log-r range that is devoid of the effects of non-stationary data.

25. (Previously Presented) The method of claim 24, further comprising:

determining a noise interval within the data series; and

if the noise interval is within a predetermined range, dividing the data series by another predetermined number and repeating the step of analyzing to produce new values for the data series.

#### REMARKS

Claims 1-25 are currently pending in the patent application. Of these claims, only claims 1, 12, and 23 are independent claims. Claims 2-11, 13-22, and 24-25 respectively depend from these claims. Claims 1, 5-12, and 15-25 are rejected under the judicially created doctrine of obviousness-type double patenting. Claims 1-3, 5-14, and 16-25 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,215,697 ("Demetrescu"). Claims 4 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,720,294 ("Skinner"). Applicant respectfully requests allowance of all the pending claims in view of the subsequent remarks regarding the above-mentioned independent claims.

#### I. Remarks re non-statutory double patenting rejection

Claims 1, 5-12, and 15-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,076,288. Applicants respectfully disagree. However, in an effort to expedite prosecution, applicants submit with this Response a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) relative to U.S. Patent No. 7,076,288. It is believed that this obviates the present rejection pursuant to M.P.E.P. § 804.02.

#### II. Remarks re 35 U.S.C. §103 rejections

In the Office Action mailed August 8, 2006 ("Office Action"), claims 1-3, 5-14, and 16-25 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over *Demetrescu*.

Claims 4 and 15 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over *Skinner*.

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For a prima facie case of obviousness, there must be a motivation to modify the reference or combine reference teachings, and the cited references must teach or suggest all of the claim limitations with a reasonable expectation of success. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). In order for a reference to be effective prior art under 35 U.S.C. § 103, it must provide a motivation whereby one of ordinary skill in the art would be led to do that which the applicant has done. See Stratoflex Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). The Patent Office has the burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness, which can be satisfied only by showing some objective teaching in the prior art would lead one to combine the relevant teachings of the references. See In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). It is axiomatic that in order for a prima facie case of obviousness to be properly presented, a motivation to combine the references either must exist expressly or implicitly. See In re Rouffet, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998).

Demetrescu does not render independent claims 1, 12, or 23 obvious for at least the reason that all the claim limitations have not been met. Demetrescu discloses an aperiodic analysis system, as for the electroencephalogram. More specifically,

the present invention is directed to a system whereby EEG information is decoded and presented in a concentrated format indicated above, so as to preserve the individual characteristics of the waves or waveform components. In that sense, the characteristics of the waveform which have been important for classic and traditional wave analysis are preserved in the display.

Emphasis added, See Col. 2, lines 49-56. Demetrescu discloses a display that is "a three-dimensional representation with each wave represented by a line that extends in one dimension to indicate amplitude. The position of the line in another dimension indicates the 491709

period or equivalent frequency, and its position in the third dimension indicates the time of occurrence of the wave." See Abstract and FIG. 2. In other words, this reference discloses an system that produces a display indicative of electromagnetic wave attributes (e.g., amplitude, period, or time of occurrence). Essentially, Demetrescu provides a system that allows for display of a large amount of EEG data in a compact format.

#### A. Claims 1 and 23

In rejecting claims 1 and 23, the Office Action on page 3 specifically references the portion of the *Demetrescu* description describing EEG spike detection, contained in col. 11, lines 30-61. This portion of *Demetrescu* teaches that an "EEG input signal is first differentiated by a differentiator 112, the output of which is applied to five distinct comparator circuits 114, 116, 118, 120, and 122." See Col. 11, lines 31-34. In this step, *Demetrescu* teaches determining a slope of an EEG signal, in this case  $\mu$ V/sec. The determined slope is then provided to comparator circuits. "The comparators operate with respect to different predetermined levels of slope for the differentiated value of the EEG." See Col. 11, lines 34-36. "As the differentiator 112 provides an output which is proportional with the slope of the input signal, the comparators 114, 116, 118, 120, and 122 are simple amplitude or threshold circuits to provide a binary signal, the high level of which is indicative of a predetermined degree of slope in the EEG." See Col. 11, lines 52-57.

The function of the *Demetrescu* comparators is to determine if the slope of the EEG signal (provided by the differentiator) is larger than, or smaller than, a predetermined value. If the slope meets the threshold requirement of a comparator, the system determines if the signal having that slope continues for a certain period of time to ensure that the EEG signal is increasing (or decreasing) long enough to attain an amplitude that could be associated with a

spike. "The separate comparators are employed to enable the use of separate time-test circuits so as to accommodate the imposition of different time criteria for testing the occurrence of a spike in accordance with the standards indicated above." See Col. 11, lines 57-61.

Ultimately, in *Demetrescu*, if the EEG signal maintains the slope that met the predetermined value for a sufficient time, the system will determine if the signal was sufficiently isolated in time to increase the probability that the EEG signal is a spike.

The comparator 114 is connected directly to an "and" gate 126 and additionally is connected to that gate through an amplifier 128 and a single shot 130. The single shot 130 consists of a monostable multivibrator providing the low state of a binary signal as an output, except when an input triggers the single shot to provide the binary ouput at a high level for a predetermined interval. As designated, the interval of the single shot 130 is five milliseconds. The output from the gate 126 is provided to a single shot 132 which is in turn connected to an "and" gate 134 which supplies the trigger signal T indicative of a spike.

See Col. 11, lines 62-68 through Col. 12, lines 1-5.

At no point in *Demetrescu* is a determined slope set equal to a predetermined threshold value as recited in claims 1 and 23 of the present application. Further, Applicant respectfully disagrees with the Office Action on page 5 where it states the "slope of the input signal as disclosed in *Demetrescu* does appear to be determined and used in a sufficiently similar manner to conclude that it is obvious to determine whether a slope is less than a predetermined value."

In fact, if the system of *Demetrescu* were to implement the limitation of setting a slope equal to a threshold value as currently claimed, the system of *Demetrescu* would no longer serve its intended purpose. In the description of the EEG spike detection as described above and in *Demetrescu*, if one of the comparators 116, 118, 120, or 122 were to set the determined slope of an EEG signal equal to the threshold value of the comparator, it would significantly reduce the

ultimate amplitude of the potential spike. If comparator 114 were to determine that the slope was either less than -800  $\mu$ V/sec or greater than +800  $\mu$ V/sec, which predetermined value would the slope be set to? -800 or +800? Also, as seen in FIG. 8, an output is required from at least four comparators. If the slope were constantly set to the predetermined threshold value of one comparator, it is possible that none of the other comparators would ever provide an output indicating a spike to the spike trigger 134. For example, if an EEG signal had a slope of +2200  $\mu$ V/sec, would the slope be set to +800 by comparator 114 or +2000 by comparator 116? In either case, the slope would be prevented from reaching the +3000  $\mu$ V/sec required to generate an output from comparator 122, ultimately preventing the EEG signal from being correctly identified as a spike and displayed as such.

Furthermore, setting a determined slope equal to a predetermined value runs contrary to the teachings of *Demetrescu* as *Demetrescu* seeks to provide an easy to read display of a large quantity of EEG data. If the amplitudes of potential spikes are prematurely reduced as part of the system, the display system has little utility, as the spike might be discarded as noise or as a non-spike wave. Not only does *Demetrescu* fail to disclose setting a determined slope equal to a predetermined threshold value, *Demetrescu* specifically teaches away from altering the slope, less the ultimate EEG display be misleading.

Additionally, the contributions provided by the present application are not made obvious in light of what was known to one of ordinary skill in the art. The detection of a slope in the *Demetrescu* system, which is used to identify a spike in an EEG data stream, is very different than the detection of a slope in the present application. The present application can determine the "degrees of freedom" of an entire EEG data stream with a PD2i algorithm. The slope (dV/dt)

running through a time series in *Demetrescu* is unrelated to the slope (PD2i) of a correlation integral of the whole time series as used in the present application. While both *Demetrescu* and the present application utilize detection and comparison of a "slope," the definitions of the slopes are very different. The Applicant respectfully puts forth that it is unreasonable to state that because one has knowledge about the use of slope in dV/dt, that it would be obvious to one skilled in the art how to use a slope in the correlation integral of the PD2i. The comparing of this slope to a threshold value and setting that slope equal to the threshold value is neither taught by *Demetrescu* nor made obvious by *Demetrescu* and would not have been developed based on what is taught in *Demetrescu*.

Applicant respectfully requests withdrawal of this rejection.

#### B. Claim 12

In rejecting claim 12, the Office Action on pages 3 and 4 specifically references the portion of the *Demetrescu* description describing EEG spike detection, contained in col. 11, lines 30-61, described in detail above, and the portion of *Demetrescu* describing the reasoning behind time testing, contained in col. 12, lines 37-42. *Demetrescu* does not teach determining if a data series is within a predetermined range and subsequently dividing the data series by a predetermined number as recited in claim 12. This limitation is directed at reducing noise in the data series. The Office Action on page 4 addressed this limitation by referring to the "selectivity of comparator 116" in *Demetrescu*. *Demetrescu* is referring to a property of an EEG spike. If an EEG signal does not maintain the slope above (or below) the comparator threshold for a predetermined period of time (for example, time test 144), then the EEG signal will not achieve

an amplitude necessary to be deemed a spike, and can be discarded as a short wave, in other words, random noise.

Nowhere in the disclosure of *Demetrescu* is taught the dividing of a data series by a predetermined number to reduce noise. Furthermore, this noise reduction technique provided by the present application is not made obvious in light of what was known to one of ordinary skill in the art. To illustrate how this limitation is not obvious to one skilled in the art, reference is made to the present application in the context of electrocardiogram data and arrhythmic death. Figure 3 of the present application illustrates the examination of low-level noise in the background of R-R interval data (RR) obtained from an electrocardiogram (ECG). This is a representative illustration of what is exhibited in the subsequent figures and tables. Figure 3 shows a magnified portion of a 15-minute RR interval series made from the ECG. Exhibited on the same +10 to -10 integer scale are two 20 heartbeat series; the bold series is within the +/-10 limits and is marked OK, whereas the non-bold series shows excursions of the noisy background that exceed these limits.

The present application provides a method for noise reduction based on what is observed in 20-Heartbeat windows. If a 20-beat noise amplitude is OK, then the 15-min RR data series is not divided by a predetermined number, and if the 20-beat noise exceeds the stated limit, then the data series is divided by a predetermined number. In other words, if the predetermined number is two, a noise-bit is removed (i.e., the amplitude for the entire data series is reduced by 50%).

Tables 1A and 1B show the effects of dividing a data series by a predetermined number of two for the PD2i of heartbeats in the prediction of Arrhythmic Death (AD and non-AD). This is shown with other linear and nonlinear algorithms that have been used for the analysis of

interval data. It is clear that PD2i, using the noise reduction technique of the present application, is far superior to other algorithms used previously in the field to predict arrhythmic death, as it has high statistically-significant Sensitivity (SEN) and Specificity (SPE) in all cardiac subgroups. The noise reduction method accomplished by dividing a data series by a predetermined number is neither taught by *Demetrescu* nor made obvious by *Demetrescu* and would not have been developed based on what is taught in *Demetrescu*.

Accordingly, Applicant respectfully requests withdrawal of this rejection.

#### C. Claims 1, 12, and 23

In rejecting claims 1, 12, and 23, the Office Action on page 3 specifically references the portion of the *Demetrescu* description describing EEG spike detection, contained in col. 11, lines 30-61 and described in detail above. *Demetrescu* does not teach using the data series to detect or predict the onset of a cerebral disorder, as recited in claims 1, 12, and 23. The Office Action states on page 3 that the:

separate comparators are usable to enable separate time-test circuits to accommodate the imposition of different time criteria for testing the occurrence of a spike in accordance with the standards to indicate the onset of a cerebral disorder.

This describes the ability of the *Demetrescu* system, through the use of multiple comparators with multiple time tests, to accurately discern if an EEG signal is a spike. This is not the same as teaching the use of a data series to "detect or predict the onset of the cerebral disorder" as recited in claims 1, 12, and 23 of the present application.

Demetrescu does not teach the use of a data processing routine (for example, the PD2i), to create a data series usable to detect or predict anything, to include a cerebral disorder.

Demetrescu's teachings are directed toward displaying large quantities of EEG signals in a compact format. The use of the data series in Demetrescu is described in col. 17, lines 62-68,

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a system of FIG. 1 as disclosed above will develop a static image, stored on the storage tube display 18 which is in the form described with reference to FIG. 2. Using a variety of well known structures as the hard-copy unit 20, the image or picture may be reproduced on a sheet of paper to provide a permanent record. Of course, as explained above, the picture is a considerably more perceivable form for a significant amount of EEG data. As a consequence, neurologists and other persons may perceive an analysis of the EEG by reviewing a few sheets rather than to scan through a considerable length of the EEG as a recorded waveform.

Essentially, the data series of *Demetrescu* are displayed on a screen or printed out for later viewing by a neurologist. Therefore, *Demetrescu* does not teach, nor render obvious, the limitation of "using the data series to detect or predict the onset of the cerebral disorder."

Furthermore, the contributions provided by the present application are not made obvious in light of what was known to one of ordinary skill in the art. The display output in the Demetrescu system simply highlights the location of likely eleptogenic spikes in an EEG signal so that a clinician can later diagnose epilepsy. This display can not inform a clinician skilled in the art about the number of "degrees of freedom" in the EEG at that moment, as in the present application. "Spike location" can not predict "degrees of freedom," as they are completely unrelated entities, with the latter utilizing a correlation integral which is not utilized by the former. The present application can suggest how many independent generators are involved in the genesis of any biological signal at each moment in time (i.e., the time-dependent degrees of freedom). Applicant respectfully puts forth that this information simply would not be obvious to one skilled in the art from examination of the Demetrescu system. The use of the data series to

predict the onset of a cerebral disorder is neither taught by *Demetrescu* nor made obvious by *Demetrescu* and would not have been developed based on what is taught in *Demetrescu*.

Applicant respectfully requests withdrawal of this rejection.

#### D. Claims 4 and 15

In the Office Action, Claims 4 and 15 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over *Demetrescu* in view of *Skinner*. Since this obviousness rejection only applies to these dependent claims and the Applicant asserts that all independent claims are allowable in light of the arguments included herein, then dependent claims 4 and 15 are allowable. Therefore, the Applicant respectfully requests withdrawal of this rejection.

#### E. No Motivation to Modify

The Federal Circuit has addressed situations in which an obviousness rejection is made based on a single reference, which occurs here. For example, the Federal Circuit ruled in *In re Kotzab*, 55 U.S.P.Q.2d 1313 (Fed. Cir. 2000), that:

Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. See B.F. Goodrich Co. v. Aircraft Breaking Sys. Corp., 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996). . . . Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. See Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617. Broad conclusory statements standing alone are not "evidence." Id.

55 U.S.P.Q.2d at 1316-17. See also WMS Gaming, Inc. v. International Game Tech., 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999); In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981) (and cases cited therein).

As another example, the Federal Circuit considered the obviousness of a claimed invention based on a single prior art reference in *Kolmes v. World Fibers Corp.*, 41 U.S.P.Q.2d 1829, 1833 (Fed. Cir. 1997):

World also argues that a prior patent of the same inventors, U.S. Patent 4,777,789, disclosed a rate of 2-24 turns per inch, which encompasses the claimed range [of 8-12 turns per inch]. World apparently argues that one skilled in the art would have known to modify that disclosed wrapping rate to that claimed in the '948 patent. Kolmes responds that World showed that there was no motivation to modify the invention disclosed in the '789 patent. We agree. The '789 patent discloses the use of wire in addition to non-metallic fibers, and World has shown no suggestion or motivation to modify the teaching of the '789 patent with regard to non-metallic fibers. Hence, it failed to prove that the invention would have been obvious in light of the '789 patent. See ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984) ("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination."). Accordingly, the district court did not err in holding that the '948 patent is not invalid on the ground of obviousness.

#### 41 U.S.P.Q.2d at 1833 (emphasis added).

Applying these legal standards to the outstanding rejection here, the Applicant respectfully submits that the rejection cannot stand at least because there is no motivation to modify the *Demetrescu* disclosure to set a slope to a predetermined value after a threshold determination, to divide a data series by a predetermined number, or to use a data series to detect or predict the onset of a cerebral disorder. The Office Action recites sections of the MPEP directed to motivation to modify a reference in the context of genus/species. The Office Action states:

It is the properties and utilities that provide real world motivation for a person of ordinary skill to make species structurally similar to those in the prior art. Dillon, 919 F.2d at 697, 16 USPQ2d at 1905; In re Stemniski, 444 F.2d 581, 586, 170 USPQ 343, 348 (CCPA 1971). The prior art need not disclose a newly discovered property in order for there to be a prima facie case of obviousness. Dillon, 919 F.2d at 697, 16 USPQ2d at 1904-05 (and cases cited therein). The slope of the input signal as disclosed in Demetrescu does appear to be determined and used in a sufficiently similar manner to conclude that it is obvious to determine whether a slope is less than a predetermined value. If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make a claimed species.

See Office Action, pages 4-5. Applicant notes that there must be a suggestion or motivation to modify the teachings of *Demetrescu* for the rejection to be viable pursuant to Federal Circuit rulings. See, e.g., In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000). Such a suggestion or motivation does not exist.

Applicant realizes that it is difficult to draw an analogy from the chemical arts to the electronic arts with genus/species motivation to modify analysis, however, there remains no basis for concluding that *Demetrescu* can be modified to produce the subject matter recited in claims 1, 12, or 23 based on the knowledge of one skilled in the art.

Applicant puts forth that *Demetrescu* does not teach a species similar to that of the present application. *Demetrescu*, as described in detail above, is directed towards display of EEG data in a compact format. The present application is not concerned with display of EEG data in a compact format, but rather the use of processed EEG data to detect or predict the onset of a cerebral disorder. The present application and *Demetrescu* are not in the same genus.

Even if it could be found that *Demetrescu* discloses a species similar to the present application, there can be no motivation to modify based on structural similarities, shared 491709

properties or utilities. Applicant puts forth that structural similarity, as used in the chemical arts, refers to the structure of a molecule or compound. If obviousness were to be found when structural similarities exist in the electronic arts, then that would render the majority of electronic and software inventions obvious. The majority of electronic and software inventions share similar structure by having a processor, a memory, a display, etc...

Molecules or compounds in the chemical arts, if found to have similar properties or utilities, can be made obvious. The Applicant understands from the Office Action that, in the present case, the similar "property" is a slope and that the slope of *Demetrescu* and the slope of the present application are used in a similar manner, the similar manner being the determination if the slope is less than a predetermined value. However, this type of comparing two numbers is not what the Applicant claims as an invention. Comparing two numbers cannot be used to render one invention obvious over a dissimilar invention, else the majority of electronic and software inventions would be obvious, since number comparison has been in existence for quite some time. What is not obvious is what the Applicant does with the slope before and after the determination of whether the slope is less than a predetermined value.

The MPEP §2144.08 II A 4(d) states that when determining whether a obviousness exists:

consider any teaching or suggestion in the reference of a preferred species or subgenus that is significantly different in structure from the claimed species or subgenus. Such a teaching may weigh against selecting the claimed species or subgenus and thus against a determination of obviousness. *Baird*, 16 F.3d at 382-83, 29 USPQ2d at 1552

Demetrescu teaches that it is preferred to not alter a determined slope. "[T]he EEG is translated to a form which preserves the characteristics traditionally recognized by neurologists in analyzing EEG's.' Emphasis added. See Col. 2, lines 33-36. To that end, to set a determined slope equal to a predetermined value runs contrary to the teachings of Demetrescu to "preserve the characteristics" of waves and to provide an easy-to-read display of a large quantity of EEG data. If potential spikes having their amplitudes prematurely reduced as part of the system, the characteristics of the waves are not preserved and the display system has little utility. Not only does Demetrescu fail to disclose setting a determined slope equal to a predetermined threshold value, Demetrescu specifically teaches away from altering the slope, less the ultimate EEG display be misleading.

Furthermore, there is no reasonable expectation of success to modify *Demetrescu* to achieve what is presently claimed. *Demetrescu's* data processing is restricted solely to determination and display of the characteristics of a wave (i.e., amplitude, frequency, etc...).

Demetrescu's slope treatment is opposite to that of the present application and there is no disclosed division of a data series by a predetermined number or the use of a data series to detect or predict the onset of a cerebral disorder. Not only would the modifications to the EEG display system of *Demetrescu* be significantly challenging to implement, but there is no indication that the modifications would result in the presently claimed methods and systems with any reasonable expectation of success. As *Demetrescu* stated himself in reference to EEG analysis:

Characteristically, the EEG is a non-periodic, stochastic phenomenon. That is, oscillations in the electrical potential cannot be predicted, consequently only current and past information is available. The absence of recurring patterns in the waveform considerably complicates analysis of the EEG, as for use in diagnosis. However, in spite of the fact that the techniques are

neither simple nor easy, neurologists have established principles and criteria for utilizing the EEG as an effective diagnostic tool.

See Col. 1, lines 10-19. Analysis of EEG signals is a complicated undertaking, significantly diminishing any reasonable expectation of success in modifying a system for displaying EEG signals to perform as a system for detecting or predicting cerebral disorders.

Accordingly, one skilled in the art would not have been motivated to modify *Demetrescu* to arrive at the claimed methods and systems because there is no teaching to make the modification. Nor is there any suggestion of such a design. Thus, a modification to set a slope to a predetermined threshold value, to divide a data series by a predetermined number, and to use a data series to detect or predict a cerebral disorder relies on hindsight reasoning because there is no suggestion or motivation to modify the teaching of *Demetrescu*. See In re Kotzab, 55

U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) ("Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference."); see also B.F. Goodrich Co. v. Aircraft Breaking Sys. Corp., 37 USPQ2d 1314, 1318 (Fed. Cir. 1996) (same). Such hindsight reasoning has been explicitly rejected by the Federal Circuit. See In re Fritch, 972 F.2d 1260, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992) ("Here, the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious."). Therefore, independent Claims 1, 12, and 23 are not rendered obvious by this reference.

Applicant respectfully requests withdrawal of this rejection.

#### III. Conclusion

Claims 1-25 are currently pending in the patent application. Of these pending claims, only claims 1, 12, and 23 are independent claims. Since the Applicant respectfully assert that these independent claims are allowable, dependent claims 2-11, 13, 22, and 24-25 are also allowable. As the Court noted in *In re Fine*, "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious."

5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988). Thus, Applicant respectfully requests allowance of all the pending claims in view of the subsequent remarks regarding the above-mentioned independent claims.

In order to support a rejection under 35 U.S.C. §103, the Examiner must establish a prima facie case of obviousness. Thus, the initial burden of proving obviousness lies with the Examiner. Since the Examiner has not identified in the Office Action a motivation to combine, a reasonable expectation of success, or a teaching/suggestion of all the claim limitations, there can be no finding of obviousness. Hence, claims 1-25 are in a condition for allowance

**2014** 

SEP 1 0 2008

ATTORNEY DOCKET NO. 22118.0002U2 APPLICATION NO. 10/767,861 **ELECTRONIC FILING** 

A Credit Card Payment in the amount of \$510.00, representing a 3-Month Extension of Time fee for small entity, is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Charley F. Frown, Registration No. 52,658

NEEDLE & ROSENBERG, P.C. 999 Peachtree Street Suite 1000 Atlanta, Georgia 30309 (678) 420-9300 (telephone) (678) 420-9301 (facsimile)

RECEIVED CENTRAL FAX CENTER SEP 1 0 2008

# ATTORNEY DOCKET NO. 22118.0002U2 PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
James Skinner	Art Unit:	3762
Application No. 10/767,861	) Confirmation No.:	2987
Filing Date: January 29, 2004	) Examiner:	George C. Manuel
For a: "METHOD AND SYSTEM FOR DETECTING AND/OR PREDICTING	)	
CEREBRAL DISORDERS"	j	

### TERMINAL DISCLAIMER

Mail Stop AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Needle & Rosenberg, P.C. Customer Number 23859

February 8, 2007

Sir:

Petitioner, Vicor Technologies, Inc., is the owner of the entire interest in the above-identified application and U.S. Patent No. 7,076,288. Petitioner hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §§154-156 and 173, as shortened by any terminal disclaimer, of U.S. Patent No. 7,076,288. Petitioner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and U.S. Patent No. 7,076,288 are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

ATTORNEY DOCKET NO. 22118.002U2 APPLICATION NO. 10/767,861

In making the above disclaimer, petitioner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. §§154-156 and 173 of U.S. Patent No. 7,076,288, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. §1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

The undersigned is empowered to act on behalf of Vicor Technologies, Inc.

I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further, that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Vicor Technologies, Inc.

Date: February 8, 2007

Name: Charley F Brown Registration No. 52,658

Title: Attorney of Record

Signature: MAIL

488658

Electronic Patent Application Fee Transmittal										
Application Number:	10	0767861								
Filing Date:	29	9√lan-2004								
Title of Invention:	M	ethod and system	for detecting	and/or predicting (	cerebral disorders					
First Named Inventor/Applicant Name:	Ja	ımes Skinner								
Filer:	CI	Charley F. Brown								
Attorney Docket Number:	22	2118.0002U2								
Filed as Small Entity										
Utility Filing Fees										
Description		Fee Code	Quantity	and/or predicting cerebral disorde	Sub-Total in USD(\$)					
Basic Filing:										
Pages:										
Claims:										
Miscellaneous-Filing:										
Petition:			. <u>.</u>							
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Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
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Electronic Ac	cknowledgement Receipt
EFS ID:	1502010
Application Number:	10767861
International Application Number:	
Confirmation Number:	2987
Title of Invention:	Method and system for detecting and/or predicting cerebral disorders
First Named Inventor/Applicant Name:	James Skinner
Customer Number:	23859
Filer:	Charley F. Brown
Filer Authorized By:	
Attorney Docket Number:	22118.0002U2
Receipt Date:	08-FEB-2007
Filing Date:	29-JAN-2004
Time Stamp:	16:46:53
Application Type:	Utility
Payment information:	

### Payment intormation:

Submitted with Payment	yes
Payment was successfully received in RAM	\$510
RAM confirmation Number	471
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

### New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

#### National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

### New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the International application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the International filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	22118.0002U2  EXAMINER  MANUEL GEORGE C  ART UNIT PAPER  3762	CONFIRMATION NO.
10/767,861	01/29/2004	James Skinner	22118.0002U2	2987
23859	7590 08/08/2006		EXAM	NER
NEEDLE & SUITE 1000	ROSENBERG, P.C.		MANUEL C	IEORGE C
	ree street		ART UNIT	PAPER NUMBER
atlanta,	GA 30309-3915		3762	
			DATE MAILED: 08/08/2006	i

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Comments	10/767,861	SKINNER, JAMES
Office Action Summary	Examiner	Art Unit
	Office Action Summary    10/767,861   SKINNER, JAMES	
- The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address –
WHICHEVER IS LONGER, FROM THE MAILING D/  - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for repty is specified above, the maximum statutory period v  - Fallure to repty within the set or extended period for repty will, by stabute	ATE OF THIS COMMUNICATION  18(a). In no event, however, may a reply be lim  will apply and will expire SIX (6) MONTHS from  , cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on 5/18/	<u>′06</u> .	
2a)☐ This action is FINAL. 2b)☒ This	action is non-final.	
3) Since this application is in condition for allowar	nce except for formal matters, pro	secution as to the merits is
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.
Disposition of Claims		
4) Claim(s) 1-25 is/are pending in the application.		
4a) Of the above claim(s)is/are withdray	wn from consideration.	
5) Claim(s) is/are allowed.		•
8) Claim(s) are subject to restriction and/o	r election requirement.	
Application Papers		
9) The specification is objected to by the Examine	r.	
10) ☐ The drawing(s) filed on is/are: a) ☐ acc	epted or b) $\square$ objected to by the $\mathfrak l$	Examiner.
11) I he oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.
Priority under 35 U.S.C. § 119		
	priority under 35 U.S.C. § 119(a)	)-(d) or (f).
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application from the International Bureau	ı (PCT Rule 17.2(a)).	
* See the attached detailed Office action for a list	of the certified coples not receive	ed.
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Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)
2) Notice of Draftsperson's Palent Crawing Review (PTO-948)	Paper No(s)/Mall Da	nie
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Art Unit: 3762

Page 2

#### **DETAILED ACTION**

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 987, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-12 and 15-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,076,288. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to obvious variations of detecting or predicting anomalies or disorders. Cerebral disorders are an obvious variation of a cerebral epileptic seizure.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3762

Page 3

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth In section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the Invention was made.

Claims 1-3,5-14 and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demetrescu '697.

Demetrescu discloses analyzing data comprising EEG data. Comparator circuits 114, 116, 118, 120 and 122 operate with respect to different predetermine levels of slope for the differentiated value of the EEG. The comparator circuits function for increasing slope signals; however, they may selectively operate with respect to signals having either a positive or a negative direction of change. One or ordinary skill in the art would have found it obvious to determine whether a slope of the data series is smaller than a predetermine value for the comparator circuits and set the slope to the predetermined value because Demetrescu teaches the differentiator 112 provides an output which is proportional with the slope of the Input signal and the comparators are threshold circuits which indicate a predetermined degree of slope in the EEG. The separate comparators are usable to enable separate time-test circuits to accommodate the imposition of different time criteria for testing the occurrence of a spike in accordance with the standards to indicate the onset of a cerebral disorder.

Regarding claims 2 and 3, one of ordinary skill in the art would have found it obvious to set the slope criteria for detecting bovine spongioform encephalitis or

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Page 4

Alzheimer's disease because these diseases have distinct EEG waveforms detectable with the differentiator and comparators set forth in the Demetrescu device.

Demetrescu teaches the selectivity of comparator 116 eliminates the effect of random noise. One of ordinary skill in the art would have found it obvious to divide the EEG data series by two because Demetrescu further teaches short waves generated by random noise do not normally have a duration of six milliseconds and, accordingly, are discriminated in that they will not trigger the single shot 140.

Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demetrescu '697 in view of Skinner '294.

Demetrescu meets all of the claim limitations as discussed above except for using the data processing routine for the EEG data.

Skinner teaches using the data processing routine of claims 4 and 15.

One of ordinary skill in the art would have found it obvious to use the data processing routine of Skinner with the device of Demetrescu for processing the EEG data because Skinner teaches the algorithm is capable of analyzing EEG signals.

#### Response to Arguments

Applicant's arguments filed 5/18/06 have been fully considered but they are not persuasive. The assertion that a case of prima facia obviousness has not been met is without merit. It is the properties and utilities that provide real world motivation for a person of ordinary skill to make species structurally similar to those in the prior art.

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Page 5

Dillon, 919 F.2d at 697, 16 USPQ2d at 1905; In re Stemniski, 444 F.2d 581, 586, 170 USPQ 343, 348 (CCPA 1971). The prior art need not disclose a newly discovered property in order for there to be a prima facie case of obviousness. Dillon, 919 F.2d at 697, 16 USPQ2d at 1904-05 (and cases cited therein). The slope of the input signal as disclosed in Demetrescu does appear to be determined and used in a sufficiently similar manner to conclude that it is obvious to determine whether a slope is less than a predetermined value. If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make a claimed species.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

George Manuel Primary Examiner ţ

Index of Claims		Applic	atio	n/Cont	rol No			App	plic	ant( min	s)/P	aten n	t under
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41	Search Notes			Application/Com	No. Ap	Applicant(s)/Patent under Reexamination				
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PATENT
PAGE 1 OF 11



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
James Skinner	Art Unit:	3762
Application No. 10/767,861	) Confirmation No.	2987
Filing Date: January 29, 2004	) Examiner:	George C. Manuel
For a: "METHOD AND SYSTEM FOR DETECTING AND/OR PREDICTING CEREBRAL DISORDERS"	) ) )	

## AMENDMENT AND RESPONSE TO OFFICE ACTION

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 NEEDLE & ROSENBERG, P.C. 999 Peachtree Street, Suite 1000 Atlanta, Georgia 30309 Customer Number 23859

Sir:

In response to the November 15, 2005 Office Action that issued in the above-identified patent application, and in accordance with the revised amendment practice outlined in revised 37 C.F.R § 1.121, please amend the application as indicated. A Current Claim List begins on page 2 of this paper. Remarks begin on page 6 of this paper.

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### CURRENT CLAIM LIST

This listing of claims will replace all prior versions, and listings, of claims in the application.

(Original) A method of detecting or predicting a cerebral disorder, comprising the steps of:
 analyzing input biological or physical data using a data processing routine including a set
 of application parameters associated with biological data correlating with the cerebral disorder to
 produce a data series,

determining whether a slope of the data series is smaller than a predetermined value; if the slope is less than a predetermined value, setting the slope to a predetermined number; and

using the data series to detect or predict the onset of the cerebral disorder.

- 2. (Original) The method of claim 1, wherein the cerebral disorder is bovine spongioform encephalitis.
- 3. (Original) The method of claim 1, wherein the cerebral disorder is Alzheimer's disease.
- 4. (Original) The method of claim 1, wherein the data processing routine uses the following algorithm to produce a data series PD2i:

PD2i  $\subseteq \log C(n, r, nref^*)/\log r$ 

where  $\subseteq$  means scales as, C is the correlation integral for PD2i in which n equals the data length, r equals the scaling range, and nref\* equals a location of the reference vector for estimating the scaling region slope of log C/log r in a restricted small log-r range that is devoid of the effects of non-stationary data.

- 5. (Original) The method of claim 1, wherein the predetermined value is approximately 0.5.
- 6. (Original) The method of claim 1, wherein the predetermined number is zero.

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7. (Original) The method of claim 1, further comprising:

determining a noise interval within the data series; and

if the noise interval is within a predetermined range, dividing the data series by another predetermined number and repeating the step of analyzing to produce new values for the data series.

- 8. (Original) The method of claim 7, wherein the other predetermined number is two.
- 9. (Original) The method of claim 7, wherein the predetermined range is -x to +x, where x is any number.
- 10. (Original) The method of claim 9, wherein the predetermined range is -5 to +5.
- 11. (Original) The method of claim 1, wherein the input biological or physical data includes electrophysiological data.
- 12. (Original) A method of detecting or predicting cerebral disorder, comprising the steps of: analyzing input biological or physical data using a data processing routine including a set of application parameters associated with biological data correlating with the cerebral disorder to produce a data series;

determining a noise interval within the data series; and

if the noise interval is within a predetermined range, dividing the data series by a predetermined number and repeating the step of analyzing to produce new values for the data series; or

if the noise interval is outside the predetermined range, using the data series to detect or predict the onset of cerebral disorder.

13. (Original) The method of claim 12, wherein the cerebral disorder is bovine spongioform encephalitis.

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- 14. (Original) The method of claim 12, wherein the cerebral disorder is Alzheimer's disease.
- 15. (Original) The method of claim 12, wherein the data processing routine uses the following algorithm to produce a data series PD2i:

PD2i  $\subseteq \log C(n, r, nrcf^*)/\log r$ 

where  $\subseteq$  means scales as, C is the correlation integral for PD2i in which n equals the data length, r equals the scaling range, and nref\* equals a location of the reference vector for estimating the scaling region slope of log C/log r in a restricted small log-r range that is devoid of the effects of non-stationary data.

- 16. (Original) The method of claim 12, wherein the predetermined number is two.
- 17. (Original) The method of claim 12, wherein the predetermined range is -x to +x, where x is any number.
- 18. (Original) The method of claim 17, wherein the predetermined range is -5 to +5.
- 19. (Original) The method of claim 12, further comprising:

  determining whether a slope of the data series is smaller than a predetermined value; and

  if the slope is less than a predetermined value, setting the slope to another predetermined
  number.
- 20. (Original) The method of claim 19, wherein the predetermined value is approximately 0.5.
- 21. (Original) The method of claim 19, wherein the other predetermined number is zero.
- 22. (Original) The method of claim 12, wherein the biological or physical data includes electrophysiological data.

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23. (New) A method of detecting or predicting a cerebral disorder selected from the group consisting of human prion diseases, cardiovascular dementia, traumatic dementia, and genetic dementia, the method comprising the steps of:

analyzing input biological or physical data using a data processing routine including a set of application parameters associated with biological data correlating with the cerebral disorder to produce a data series;

determining whether a slope of the data series is smaller than a predetermined value; if the slope is less than a predetermined value, setting the slope to a predetermined number; and

using the data series to detect or predict the onset of the cerebral disorder.

24. (New) The method of claim 23, wherein the data processing routine uses the following algorithm to produce a data series PD2i:

PD2i  $\subseteq \log C(n, r, nref*)/\log r$ 

where  $\subseteq$  means scales as, C is the correlation integral for PD2i in which n equals the data length, r equals the scaling range, and nref\* equals a location of the reference vector for estimating the scaling region slope of log C/log r in a restricted small log-r range that is devoid of the effects of non-stationary data.

25. (New) The method of claim 24, further comprising:

determining a noise interval within the data series; and

if the noise interval is within a predetermined range, dividing the data series by another predetermined number and repeating the step of analyzing to produce new values for the data series.

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### REMARKS

Claims 1-22 are currently pending in the patent application. Claims 23-25 have been added with this Amendment. Of these claims, only claims 1, 12, and 23 are independent claims. Claims 2-11, 13-22, and 24-25 respectively depend from these claims. As the Court noted in In re Fine, "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious." 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988). Using this same rationale, dependent claims cannot be anticipated if the independent claims from which they depend are not anticipated. Since the Applicant respectfully asserts that these independent claims are allowable, dependent claims 2-11, 13-22, and 24-25 are also allowable. Thus, Applicant respectfully requests allowance of all the pending claims in view of the subsequent remarks regarding the above-mentioned independent claims.

## I. Remarks re recently added Claims 23-25

There is clear support for new Claims 23-25 in the current patent application. More specifically, the support for these claims can be found at least in the detailed description on page 23, lines 4-15. Therefore, the Applicant asserts that newly added Claims 23-25 do not constitute new matter and should be entered in the current application.

## II. Remarks re 35 U.S.C. §103 rejections

In the Office Action mailed November 15, 2005 ("Office Action"), Claims 1-3, 5-15, and 16-22 arc rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 4,215,697 issued to Demetrescu on August 5, 1980 ("Demetrescu"). Claims 4 and 15 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Demetrescu in view of U.S. Patent No. 5,720,294 issued to James Skinner on February 24, 1998 ("Skinner"). Since the obviousness rejection to the independent claims only applies to Demetrescu and the allowability of the dependent claims necessarily follows allowable independent claims (see In re Fine, Id.), the remaining comments regarding obviousness will focus on Demetrescu.

For a prima facie case of obviousness, there must be a motivation to modify the reference or combine reference teachings, and the cited references must teach or suggest all of the claim

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limitations with a reasonable expectation of success. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). In order for a reference to be effective in prior art under 35 U.S.C. § 103, it must provide a motivation whereby one of ordinary skill in the art would be led to do that which the applicant has done. See Stratoflex Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983). The Patent Office has the burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness, which can be satisfied only by showing that some objective teaching in the prior art would lead one to combine the relevant teachings of the references. See In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

The Applicant understands the logic of the obviousness rejection to be as follows: the claims are alleged to be obvious in view of Demetrescu in combination with a general knowledge that one skilled in the art would allegedly possess. This appears to follow from the statement in the Office Action: "Demetrescu discloses... One of ordinary skill in the art would have found it obvious..." See Office Action at page 2. Thus, the obviousness rejection is based upon the "conventional" aperiodic analysis system provided by the disclosure of Demetrescu and the general knowledge of a skilled person in the art. As argued below, there is no legal basis for establishing that this reference in combination with a general knowledge that one skilled in the art would possess makes the claimed invention obvious.

A review of the primary reference shows that it discloses an aperiodic analysis system, as for the electroencephalogram. More specifically, "present invention is directed to a system whereby EEG information is decoded and presented in a concentrated format indicated above, so as to preserve the individual characteristics of the waves or waveform components. In that sense, the characteristics of the waveform which have been important for classic and traditional wave analysis are preserved in the display." See Col. 2, lines 49-56. Demetrescu discloses a display that is "a three-dimensional representation with each wave represented by a line that extends in one dimension to indicate amplitude. The position of the line in another dimension indicates the period or equivalent frequency, and its position in the third dimension indicates the time of occurrence of the wave." See Abstract. In other words, this reference discloses an analysis system that produces a display indicative of electromagnetic wave attributes (e.g., amplitude, period, or time of occurrence).

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It is axiomatic that in order for a prima facie case of obviousness to be properly presented, the cited references must teach, or suggest, all of the claim limitations. See In re Vaeck, Id. While it is true that a single reference can serve as the basis for prior art rejection, it must be obvious to a person of ordinary skill to modify the single reference to produce the invention as claimed. Common knowledge or common sense cannot serve as the basis for meeting this requirement, rather there must be some specialized knowledge and expertise documented on the record; "common knowledge and common sense, even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority." See In re Lee, 277 F.3d 1338 (Fed. Cir. 1984). Even with the assertions made in the Office Action on pages 2-3, there is no basis for concluding that Demetrescu can be modified to produce the subject matter recited in Claim 1 and Claim 12 based on the knowledge of a skilled artisan. The shortcomings in these assertions are more clearly indicated below.

The subject matter recited in Claim 1 is neither taught nor suggested by Demetrescu. Claim 1 is directed to a method of detecting or predicting a cerebral disorder that comprises the steps of: analyzing input biological or physical data using a data processing routine including a set of application parameters associated with biological data correlating with the cerebral disorder to produce a data series; determining whether a slope of the data series is smaller than a predetermined value; if the slope is less than a predetermined value, setting the slope to a predetermined number; and using the data series to detect or predict the onset of the cerebral disorder. Though stated in the Office Action, Demetrescu neither discloses nor suggests the above-mentioned subject matter.

The subject matter recited in Claim 12 is neither taught nor suggested by Demetrescu. Claim 12 is directed to a method of detecting or predicting cerebral disorder, comprising the steps of: analyzing input biological or physical data using a data processing routine including a set of application parameters associated with biological data correlating with the cerebral disorder to produce a data series; determining a noise interval within the data series; and if the noise interval is within a predetermined range, dividing the data series by a predetermined number and repeating the step of analyzing to produce new values for the data series; or if the noise interval is outside the predetermined range, using the data series to detect or predict the

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onset of the cerebral disorder. Though stated in the Office Action, Demetrescu neither discloses nor suggests the above-mentioned subject matter.

Even though the Office Action does not include a clear indication of how Demetrescu suggests the subject matter recited in claim 1 and claim 12, the Applicant includes the following explanation for the sole purpose of being fully responsive to statements on pages 2-3 of the Office Action. Moreover, the Applicant reiterates that as mentioned above with regard to the individual claims Demetrescu does not disclose the subject matter recited in claim 1 and claim 12 and cannot be made obvious by this reference. With this in mind, the remaining description will address statements about what Demetrescu supposedly discloses.

Even if Demetrescu discloses analyzing EEG data, this reference neither teaches nor suggests the subject matter of claim 1 or claim 12. While the Applicant concedes that Demetrescu analyzes EEG data, neither claim 1 nor claim 12 include simply analyzing EEG data. In fact, the analysis described in Demetrescu never mentions any of the factors associated with analyzing data including, but not limited to, application parameters, a cerebral disorder, or even a data series. Moreover, these factors are not within the common knowledge of one skilled in the art. Therefore, Demetrescu cannot teach or suggest the subject matter of claim 1 or claim 12 for at least the reason that it does not suggest all of the recited claim limitations.

According to page 2 in the Office Action, Demetresch discloses comparator circuits 114-122 that supposedly operate with respect to different predetermined levels of slope for the differentiated value of the EEG. The Applicant concedes that these comparators receive the EEG output from a differentiator. However, the conclusion that it is obvious to determine whether a slope of the data series is smaller than a predetermined value is erroneous. While it is somewhat unclear exactly what is meant by comparators "function for increasing slope signals" and that they may "selectively operate," the above-mentioned conclusion does not necessarily follow from these assertions.

As mentioned above with regard to *In re Gordon*, there must be more than common knowledge, "lest the haze of so-called expertise acquire insulation from accountability." *Id.* at 1344-1345. Even though comparators receive the EEG output from a differentiator, there is nothing to suggest that a skilled artisan would even consider a data series, a predetermined value, or the relation of a slope to that predetermined value with these comparators. Moreover, nothing

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in Demetrescu suggests these factors either. Demetrescu does include a differentiator 112 with an output proportional to the slope of the input. If the input to a comparator is proportional to the input of the differentiator as suggested in the Office Action, one still cannot conclude that is obvious to determine whether a slope is less than a predetermined value. In fact, it is unclear from the Office Action what predetermined value Demetrescu discloses. Therefore, Demetrescu cannot teach or suggest the subject matter of claim 1 or claim 12 for at least the reason that it does not suggest all of the recited claim limitations.

In order to support a rejection under 35 U.S.C. §103, the Examiner must establish a prima facie case of obviousness. Thus, the initial burden of proving obviousness lies with the Examiner. Since the Examiner has not identified in either the Office Action a motivation to combine, a reasonable expectation of success, or a teaching/suggestion of all the claim combine, there can be no finding of obviousness. Hence, claim 1 and claim 12 are in a limitations, there can be no finding of obviousness. Hence, claim 1 and claim 12 are in a condition for allowance. It necessarily follows that all claims, which depend from these claims are also allowable. See In re Fine, Id. Consequently, claims 1-22 are in a condition for allowance.

In the Office Action, Claims 4 and 15 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Demetrescu in view of U.S. Patent No. 5,270,214 issued to James Skinner on January 8, 2004 on behalf of Richard Appelt et al. ("Appelt"). Since this obviousness rejection only applies to these dependent claims and the Applicant asserts that independent claims 1 and 35 are allowable in light of the arguments included herein, then dependent Claims 4 and 15 are allowable based on *In re Fine*, which was cited above. Therefore, the Applicant respectfully traverses the rejection of these claims.

### **CONCLUSION**

Claims 1-25 are currently pending in the patent application. Of these pending claims, only claims 1, 12, and 23 are independent claims. Since the Applicant respectfully assert that these independent claims are allowable, dependent claims 2-11, 13, 22, and 24-25 are also allowable. Thus, Applicant respectfully request allowance of all the pending claims in view of the above-mentioned remarks regarding the above-mentioned independent claims.

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In order to support a rejection under 35 U.S.C. §103, the Examiner must establish a prima facie case of obviousness. Thus, the initial burden of proving obviousness lies with the Examiner. Since the Examiner has not identified in the Office Action a motivation to combine, a reasonable expectation of success, or a teaching/suggestion of all the claim limitations, there can be no finding of obviousness. Hence, claims 1-25 are in a condition for allowance

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$685.00, representing \$75.00/additional claims fee; \$100.00/additional independent claim fee; and \$510.00/3-Month Extension of Time fee, is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Charley F Brown, Registration No. 52,658

NEEDLE & ROSENBERG, P.C. 999 Peachtree Street Suite 1000 Atlanta, Georgia 30309 (678) 420-9300 (telephone) (678) 420-9301 (facsimile)

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U.S. Patent and Trademark Office

Part of Paper No. 20051113



### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Fatest and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Bo. 1450 Alexanda, Vennin 22313-1450

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,861	01/29/2004	James Skinner	22118.0002U2	2987
23859 7	590 11/15/2005		EXAM	NER
NEEDLE & F SUITE 1000	ROSENBERG, P.C.	1	MANUEL, C	EORGE C
999 PEACHTR		,	ART UNIT	PAPER NUMBER
ATLANTA, G	A 30309-3915		3762	•
			DATE MAILED: 11/15/2005	i

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	L Amalia - Mai
	1	Applicant(s)
Office Action Summer.	10/787,861	SKINNER, JAMES
Office Action Summary	Examiner	Art Unit
	George Manuel	3762
- The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet	with the correspondence address -
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the melting date of this communication If NO period for reply is specified above, the maximum statutory period - Falture to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mal earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUN 1.138(a). In no event, however, may not will apply and will expire \$1% (6) MK	IICATION. a reply be timely filed  DITH'S from the malling date of this communication.
Status		
1) Responsive to communication(s) filed on		
_	 nis action is non-final,	
3) Since this application is in condition for allow		there prosecution as to the mosts is
closed in accordance with the practice under	Ex parte Quavie, 1935 C.	D. 11. 453 O.G. 213
Disposition of Claims		
4)⊠ Claim(s) <u>1-22</u> is/are pending in the application	nn	
4a) Of the above claim(s) is/are withdr		
5) Claim(s) is/are allowed.	awn from consideration,	
6) Claim(s) 1-22 is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and	or election requirement	
	or oldston roden ement.	
Application Papers		
9)☐ The specification is objected to by the Examin	ner.	
10) ☐ The drawing(s) filed on is/are: a) ☐ ac	cepted or b) objected to	by the Examiner.
Applicant may not request that any objection to the		
Replacement drawing sheet(s) including the corre	ction is required if the drawin	g(s) is objected to, See 37 CFR 1.121(d).
11) The cath or declaration is objected to by the E	Examiner. Note the attache	ed Office Action or form PTO-152.
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreig	in priority under 35 U.S.C.	S 119(a)-(d) or (f)
a) ☐ All b) ☐ Some * c) ☐ None of:	p	3 1 10(2)-(2) 51 (1)-
1. Certified copies of the priority documer	nts have been received.	
2. ☐ Certified copies of the priority documer		Application No.
3. Copies of the certified copies of the pri		
application from the International Burea	au (PCT Rule 17.2(a)).	
* See the attached detailed Office action for a lis		t received.
Attachment(s)		
1) X Nolice of References Cited (PTO-892)	4) 🔲 Interview	Summary (PTO-413)
1) E 110100 011000 01100 (1 10 002)		
2) 🔲 Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No	s)/Mail Date
<ul> <li>Notice of Draftsparson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 7/30/04, 69/05.</li> </ul>	Paper No.  5) Notice of  6) Other:	Informal Patent Application (PTO-152)

Art Unit: 3762

Page 2

#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3,5-14 and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Demetrescu '697.

Demetrescu discloses analyzing data comprising EEG data. Comparator circuits 114, 116, 118, 120 and 122 operate with respect to different predetermine levels of slope for the differentiated value of the EEG. The comparator circuits function for increasing slope signals; however, they may selectively operate with respect to signals having either a positive or a negative direction of change. One or ordinary skill in the art would have found it obvious to determine whether a slope of the data series is smaller than a predetermine value for the comparator circuits and set the slope to the predetermined value because Demetrescu teaches the differentiator 112 provides an output which is proportional with the slope of the input signal and the comparators are threshold circuits which indicate a predetermined degree of slope in the EEG. The separate comparators are usable to enable separate time-test circuits to accommodate

ATTORNEY DOCKET No. 22118.0902U2 PATENT PAGE 1 THE UNITED STATES PATENT AND TRADEMARK OFFICE RECEIVED CENTRAL FAX CENTER SEP 1 0 2008 In re Application of: 3762 Art Unit: James Skinner 2987 Confirmation No. Application No. 10/767,861 George C. Manuel Examiner: Filing Date: January 29, 2004 For a: "METHOD AND SYSTEM FOR DETECTING AND/OR PREDICTING CEREBRAL DISORDERS"

## REQUEST FOR EXTENSION OF TIME

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 NEEDLE & ROSENBERG, P.C. 999 Peachtree Street, Suite 1000 Atlanta, Georgia 30309 Customer Number 23859

Sir

It is respectfully requested that an extension of time for the period indicated below be granted in accordance with the provisions of 37 C.F.R. § 1.136 to take action required in the application identified in the caption, as reflected by the papers submitted herewith:

_		\$120.00	\$60.00*
	One Month	_	\$225.00*
	Two Months	\$450.00	
U		\$1,020.00	\$510.00*
$\boxtimes$	Three Months	•	\$795.00*
	Four Months	\$1,590.00	
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\*Small entity.

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SEP 1 0 2008

ATTORNEY DOCKET No. 22118.0002U2 PATENT PAGE 2

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$685.00, representing \$75.00/additional claims fee; \$100.00/additional independent claim fee; and \$510.00/3-Month Extension of Time fee, is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Very truly yours,

NEEDLE & ROSENBERG, P.C.

Charley F Brow

Registration No. 52,658

NEEDLE & ROSENBERG, P.C. 999 Peachtree Street Suite 1000 Atlanta, Georgia 30309 (678) 420-9300 (telephone) (678) 420-9301 (facsimile)

## CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class real in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

CasSandra D. Beiton

Date

SEP 1 0 2008

ATTORNEY DOCKET NO. 22118.0002U2 **APPLICATION NO. 10/767,861 ELECTRONIC FILING** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

	—				
In re App	lication of			)	
Jz	ames Skin	ner		)	Art Unit: 3762
Application	on No.: 10	)/767,861		)	Examiner: George C. Manuel
Filing Da	te: <b>Janu</b>	ary 29, 2004		)	Confirmation No.: 2987
D	ETECTIN	AND SYSTEM FOR IG AND/OR PREDICTI L DISORDERS	ING	) ) )	
		REQUEST FOR	EXTEN	<u>sio</u>	N OF TIME
	AMENDI ioner for P				DLE & ROSENBERG, P.C. orner Number 23859
	ia, VA 22:	313-1450	F	ebn	pary 8, 2007
Sir:					
It	is respectf	ully requested that an ext	ension of	tin	ne for the period indicated below be
granted in	accordanc	ce with the provisions of	37 C.F.R	. Se	ection 1.136 to take action required in
the applic	ation ident	ified in the caption, as re	flected b	y th	e papers submitted herewith:
		One Month	\$120.00		(\$60.00)*
		Two Months	\$450.00		(\$225.00)*
	$\boxtimes$	Three Months	\$1,020.0	0	(\$510.00)*
		Four Months	\$1,590.0	0	(\$795.00)*
		Five Months	\$2,160.0	0	(\$1,080.00)*
* Small Ent	itv				

SEP 1 0 2008

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ATTORNEY DOCKET NO. 22118.0002U2 APPLICATION NO. 10/767,861 ELECTRONIC FILING

A credit card payment in the amount of \$510.00, for payment of the Three-Month Request for Extension of Time under 37 C.F.R. §1.17(a)(3) for a small entity is enclosed.

This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Charley F Brown, Registration No. 52,658

NEEDLE & ROSENBERG, P.C. Customer Number 23859 (678) 420-9300 (678) 420-9301 (fax)

# RECEIVED CENTRAL FAX CENTER

## SEP 1 0 2008

ATTORNEY DOCKET NO. 22118.0002U2
PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)
Skinner, J.E.	) Art Unit: 3762
Application No. 10/767,861	Examiner: Manuel, G.C
Filing Date: January 29, 2004	) Confirmation No. 2987
For: METHOD AND SYSTEM FOR	)
DETECTING AND/OR PREDICTING	)
CEREBRAL DISORDER\$	)

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C. Customer Number 23859

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Information Disclosure Statement List is a listing of documents known to Applicants and/or their attorneys. In accordance with 37 C.F.R. §1.98(a)(2), copies of any cited U.S. patent or U.S. patent application publication documents are not enclosed. A copy of each of the remaining foreign patent or non-patent documents is enclosed.

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# SEP 1 0 2008

ATTORNEY DOCKET NO. 22118.0002U2 APPLICATION NO. 10/767,861 SHEET 1 OF 2

INFOR		ON DISCLOSURE STALIST  eas many sheets as necessary)	Application Number Filling Date First Named Inventor Group Art Unit Examiner Name	004						
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Examiner's	Cite	Document No.	Date	Name	Class	Subclass	Filing Date (r			
Initials	No.		00/04/00	1112 - 1 - 1		<del> </del>	appropriate			
/GM/	C1	5,215,099	05/01/93	Haberl et al.		ļ.	<del> </del>			
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/GM/	C3	Austin AR, Pawson L, Meek	S, Webster S,	. "Abnormalities of heart ra	te and r	nythm in bo	vine			
	C4	spongiform encephalopathy	, Vet Rec, 199	17, 141(14):352-357. Kolffki KD, Massanson M	*Domo	netation of	nonlinear			
	١٧٠	Braun C, Kowallik P, Freking A, Hadeler D, Kniffki KD, Meesmann M, "Demonstration of nonlinear components in heart rate variability of healthy persons.," <i>Am J Physiol</i> , 1998, 275:H1577-H1584.								
	C5	Kostelich EJ, Swinney HL, "Practical considerations in estimating dimension from time series data,"								
		Physica Scripta, 1989, 40:436-441.								
·	C6	Marwan N, Wessel N, Meyerfeldt U, Schirdewan A, Kurths J, "Recurrence-plot-based measures of complexity and their application to heart-rate-variability data," <i>Phys Rev E Stat Nonlin Soft Matter Phys</i> , 2002, 66:026702.								
	<b>C</b> 7	Skinner JE, "How the head	rules the heart,	"In: Life-threatening Arrhy	thmias Press	During Isch New York	emia and 1987, 135-151.			
	C8	Skinner JE, "Reduction of ca	Infarction, edited by D J Hearse, A S Manning and MJ Janse, Raven Press, New York, 1987, 135-151.  Skinner JE, "Reduction of cardiac vulnerability during REM sleep in the pig." In: Steep Disorders, Basic and Clinical Research, edited by M Chase and ED Weltzman, New York: Spectrum Publications, 1983,							
	C9	Skinner JE, "Regulation of of 5:88B-94B.	ardiac vulnera	bility by the cerebral defer	ise syst	em," <i>J Am</i> (	Coll Card, 1985			
	C10	Skinner JE, Douglis F, Harp functions," <i>Principles and P</i> WB Saunders Co, 1989, Ch	ractice of Sleep	o Medicine, Edited by MH	rdiovas Kryger,	cular and re T Roth and	spiratory WC Dement,			
	C11	Skinner JE, et al., "Blockade ischemic heart," Am. J. Phy	Skinner JE, et al., "Blockade of frontocortical-brain stem pathway prevents ventricular fibrillation of ischemic heart," <i>Am. J. Physiol.</i> , 1981, 240: H156-H163.							
	C12	Skinner JE, et al., "Comparison of linear-stochastic and nonlinear-deterministic algorithms in the analysis of human ECG data to predict risk of arrhythmic death." <i>Amer J Physiol</i> , (Submitted, Oct. 2004).								
	C13	Skinner JE, et al., "Sleep-st Res., 1975, 37: 342-349.	age regulation	of ventricular arrhythmias	in the u	nanesthetiz	ed pig," Circ.			
$\overline{\downarrow}$	C14	Skinner JE, et al., "Task Fo	Skinner JE, et al., "Task Force Report on sudden cardiac death and armythmias," In: Circulation, Neurobiology, and Behavior, edited by OA Smith, RA Galosy and S M Weiss, New York: Elsevier							
/GM/	C15	Winfree AT, "Electrical turb	ulence in three	-dimensional heart musde	." Scier	ice, 1994, 2	66:1003-1006.			

Examiner Signature: /George Manuel/	Date Considered:	06/05/2007
EXAMINER: Initial if reference considered, whether or not citation is	in conformance with MPEI	P 609. Draw line through citation if not in
conformance and not considered. Include copy of this form with next co	mmunication to applicant.	

### ATTORNEY DOCKET NO. 22118.0002U2 APPLICATION NO. 10/767,861 SHEET 2 OF 2

			Com	plate if Known					
IMEOR	MATIC	ON DISCLOSURE STATEMENT	Application Number	10/767,861					
INFOR		LIST	Filing Date	January 29, 2004					
		EI3 i	First Named Inventor	Skinner, J.E.					
	(Us	e os many sheets as necessary)	Group Art Unit	3762					
			Examiner Name	Manuel, G.C.					
/GM/	/GM/ C16 Winfree AT, "Sudden cardiac death: a problem in topology," Sci Am, 1983, 248:144-161.								
/GM/	The state of the s								

Examiner Signature: /George Manuel/	Date Considered: 06/05/2007
<b>EXAMINER:</b> Initial if reference considered, whether or not citation	is in conformance with MPEP 609. Draw line through citation if not in
conformance and not considered. Include conv of this form with next in	communication to a policant

### ATTORNEY DOCKET NO. 22118.0002U2 APPLICATION NO. 10/767,861 SHEET 1 OF 2

					Co	mplete if I	Cnown	
INFORMATION DISCLOSURE STATEMENT		Application Number			10/767,861			
		Filin	Filing Date		January 29, 2004			
				First	Named Inventor	r Skini	ner, J.E.	
	(Use	as many sheets as necessary)		Gro	Jp Art Unit	3762	!	
			Exa	miner Name	Manı	uel, G.C.		
	Personal		#PANENIED!	KUM			*****	
Examiner's Initials	Cite No.	Document No.	Date	Name		Class	Subclass	Filing Date or
	C1	5,215,099	06/01/93	Haberl et al.				
	C2	US 2003/0104493 A1	6/5/03	Ortel	et al.			
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Examiner's Initials	Cita No.	Foreign Patent Documen Country Code-Number-Kind Code	,		Nan	nė	Translation Yes/No	
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	C3	Austin AR, Pawson L, Meek S, Webster S, "Abnormalities of heart rate and rhythm in bovine spongiform encephalopathy," Vet Rec, 1997, 141(14):352-357.						
	C4	Braun C, Kowallik P, Freking A, Hadeler D, Kniffki KD, Meesmann M, "Demonstration of nonlinear components in heart rate variability of healthy persons.," <i>Am J Physiol</i> , 1998, 276:H1577-H1584.						
· ·	C5	Kostelich EJ, Swinney HL, "Practical considerations in estimating dimension from time series data."  Physica Scripta, 1989, 40:436-441.						
	C6	Marwan N, Wessel N, Meyerfeldt U, Schirdewan A, Kurths J, "Recurrence-plot-based measures of complexity and their application to heart-rate-variability data," <i>Phys Rev E Stat Nonlin Soft Matter Phys</i> , 2002, 66:026702.						
_	C7	Skinner JE, "How the head rules the heart," In: Life-threatening Arrhythmias During Ischemia and Infarction, edited by D J Hearse, A S Manning and MJ Janse, Raven Press, New York, 1987, 135-151.						
	C8	Skinner JE, "Reduction of cardiac vulnerability during REM sleep in the pig," In: Sleep Disorders, Basic and Clinical Research, edited by M Chase and ED Weitzman, New York: Spectrum Publications, 1983, 49-63.						
	C9	Skinner JE, "Regulation of cardiac vulnerability by the cerebral defense system," <i>J Am Coll Card</i> , 1985, 5:888-94B.						
	C10	Skinner JE, Douglis F, Harper RM, "Higher cerebral regulation of cardiovascular and respiratory functions," <i>Principles and Practice of Sleep Medicine</i> , Edited by MH Kryger, T Roth and WC Dement, WB Saunders Co, 1989, Chapter 27, 276-292.						
	C11	Skinner JE, et al., "Blockade of frontocortical-brain stem pathway prevents ventricular fibrillation of ischemic heart," <i>Am. J. Physiol.</i> , 1981, 240: H156-H163.						
	C12	Skinner JE, et al., "Comparison of linear-stochastic and nonlinear -deterministic algorithms in the analysis of human ECG data to predict risk of arrhythmic death," <i>Amer J Physiol</i> , (Submitted, Oct. 2004).						
	C13	Skinner JE, et al., "Sleep-stage regulation of ventricular arrhythmias in the unanesthetized pig," Circ. Res., 1975, 37: 342-349.						
	C14	Skinner JE, et al., "Task Force Report on sudden cardiac death and arrhythmias," In: Circulation, Neurobiology, and Behavior, edited by OA Smith, RA Galosy and S M Weiss, New York: Elsevier Biomedical Press, 1982, 309-316.						
	C15	Winfree AT, "Electrical turb	ulence in three-	dimens	ional heart musde	e," Scienc	e, 1994, 26	66:1003-1006.

Examiner Signature:	Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is	in conformance with MPEP 609.	Draw line through citation if not in
comformance and not considered. Include copy of this form with next or	mmunication to applicant.	

### ATTORNEY DOCKET NO. 22118.0002U2 APPLICATION NO. 10/767,861 SHEET 2 OF 2

		Complete if Known			
INFORMATION DISCLOSURE STATEMENT	Application Number	10/767,861			
	Filing Date	January 29, 2004			
LIOI		First Named Inventor	Skinner, J.E.		
(Use as many sheets as necessary)		Group Art Unit	3762		
		Examiner Name	Manuel, G.C.		
C16	C16 Winfree AT, "Sudden cardiac death: a problem in topology," Sci Am, 1983, 248:144-161.				
C17	Winfree AT, "When Time Breaks Down: the three-dimensional dynamics of electrochemical waves and				
1	cardiac arrhythmias," 1987, Princeton U Press, Princeton NJ, 3-124.				

Examiner Signature:	Date Considered:	
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